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| APPLICATION NO.                                                                                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/784,665                                                                                                          | 02/15/2001  | Yiqun Wang           | 1001.1412101        | 2225             |
| 11050 7590 02/14/2012<br>SEAGER, TUFTE & WICKHEM, LLC<br>1221 Nicollet Avenue<br>Suite 800<br>Minneapolis, MN 55403 |             |                      |                     |                  |
| EXAMINER                                                                                                            |             |                      |                     |                  |
| DOWE, KATHERINE MARIE                                                                                               |             |                      |                     |                  |
| ART UNIT                                                                                                            |             | PAPER NUMBER         |                     |                  |
| 3734                                                                                                                |             |                      |                     |                  |
| MAIL DATE                                                                                                           |             | DELIVERY MODE        |                     |                  |
| 02/14/2012                                                                                                          |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/784,665

**Applicant(s)**

WANG ET AL.

**Examiner**

KATHERINE DOWE

**Art Unit**

3734

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 January 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5) ☒ Claim(s) 22, 24-26, 28 and 30-37 is/are pending in the application.
- 5a) Of the above claim(s) 31-34 and 36 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 22, 24-26, 28, 30, 35 and 37 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SEC-1)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

1. The following is in response to the amendment filed January 18, 2012.
2. Claims 22, 24-26, 28, and 30-37 are currently pending, with claims 31-34 and 36 withdrawn from consideration.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 22, 24-26, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (US 4,610,665, hereinafter "Matsumoto") in view of Picha et al. (US 5,080,654, hereinafter "Picha") and Kranys (US 5,207,656).

Matsumoto discloses the invention substantially as claimed including a catheter (70), comprising: an elongate catheter shaft (71) having a proximal end, a distal end, a guidewire lumen (72) defined therethrough, and an inflation lumen (75) defined therethrough; a balloon (74) disposed adjacent the distal end of the catheter shaft, the balloon being in fluid communication with the inflation lumen; a port (76) disposed at the proximal end of the catheter shaft, the port having an opening defined therein that is in fluid communication with the inflation lumen, and a self-sealing seal member (16) attached to the end of the port and covering the opening (Fig. 16 and 17). The seal (16) is pierceable, is generally planar, and may extend laterally beyond the flanged end of the port (Fig 11). A cap (78) is coupled to the port and disposed over the seal (Fig 17). Since the seal is self-sealing to "thereby form a reliable liquid-tight or air-tight state between the catheter 15 and the valve body 16" (col 6, ll 4-5) upon withdrawal of a piercing member inserted therethrough, the seal member is capable of maintaining a vacuum with the inflation lumen.

However, Matsumoto fails to disclose the seal member is releasably attached to the flanged end. Picha discloses a self-sealing seal member (20) that is releasably attached the flanged end of a port, and the flange helps to secure the elastomeric seal in place (col. 3, In. 6-42). The seal is pierceable (col. 3, In. 12 and 56-58), is generally planar at the proximal end (Fig 4), and may extend laterally beyond the flanged end (15) of the port (Fig 4). A cap (30) is coupled to the port and disposed over the seal (Fig. 5). It would have been obvious to one of ordinary skill in the art to modify the seal assembly of Matsumoto such that the seal member was releasably attached to the flanged end, since it is a well known feature as taught by Picha and it would provide the same function of maintaining a fluid-tight seal during insertion of and after removal of an injection member. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

Furthermore, Matsumoto discloses the self-sealing seal member comprises slits (17/18) that form a fluid tight seal about the piercing member (77), wherein the slits have a minimal width and the seal (16) is formed of an elastomeric material such that upon removal of the piercing member (77) the slits form a perfect seal to prevent inflation fluid from flowing out of the balloon. However, Matsumoto teaches the slits (17/18) are pre-formed and thus fails to disclose the seal member has a solid cross-section. Kranys discloses a similar seal (24) disposed in a port of a catheter, wherein the seal comprises multiple pre-formed slits (40) to allow passage of a piercing member (Fig 2). However, Kranys additionally discloses the seal may alternatively comprise a solid cross section initially with no pre-formed opening (Fig 3). In this second embodiment, a piercing member passes through the seal (24a) to form a slit that exactly fits the transverse dimensions of the piercing member inserted therethrough (col 4, ll 1-7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was

made to modify the invention of Matsumoto such that the pre-formed slits (17/18) were replaced with a seal member having a self-sealing solid cross-section. Such a modification would further ensure fluid cannot pass through the seal unintentionally. Furthermore, it has been shown a seal with pre-formed slits and a seal with an initial solid cross section without a pre-formed opening are functional equivalents.

5. Claims 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto (US 4,610,665), Picha (US 5,080,654) and Kranys (US 5,207,656), as applied to claim 22 above, further in view of McClure (US 5,507,732) and Andrews et al. ("The Comparison of Certain Commercial Getters", 1931). Matsumoto, Picha, and Kranys disclose the invention substantially as claimed, as shown above. However, they do not disclose an inner surface of the lumen includes a chemical coating capable of binding air. McClure discloses a seal arrangement (Fig 1) for use with a typical balloon catheter (col 1, ll 11-23). McClure teaches the purpose of the seal arrangement is to hold pressure under balloon inflation as well as vacuum under balloon deflation (col 4, ll 14-17). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Matsumoto, Picha, and Kranys such that the self-sealing function of the seal member prevented the passage of fluid such that it was capable of both holding pressure under balloon inflation and holding vacuum under balloon deflation. Thus, the balloon will not unintentionally slightly deflate after time when it is intended to be inflated or slightly expand over time when it is intended to be completely deflated. Additionally, when referring to the chemical coating capable of binding air, Applicant states, "A person of ordinary skill in the art would be familiar with a getter and the use thereof according to multiple embodiments of the invention." (see specification as originally filed, page 11, lines 8-9). As evidenced by the article, "The Comparison of Certain

Commercial Getters" (1931), it is old and well known in the art to apply a chemical coating capable of binding air to a valve/sealing system to improve the vacuum capability of the device. Therefore, it would have been prima facie obvious to try modifying the combination of Matsumoto, Kranys, Picha, and McClure such that the an inner surface of the lumen includes a chemical coating capable of binding air in an attempt to provide an improved vacuum as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

### ***Response to Arguments***

6. Applicant's arguments filed January 18, 2012 have been fully considered but they are not persuasive.
7. Applicant argues the prior art of record does not teach a releasable seal member that does not include a preformed opening and is self-sealing such that the seal maintains a vacuum within the inflation lumen. The examiner respectfully disagrees. Matsumoto discloses a self-sealing seal member (16) that forms a "reliable liquid-tight or air-tight state between the catheter 15 and the valve body 16" (col 6, ll 4-5), and thus is capable of maintaining a vacuum within the inflation lumen. Kranys teaches a seal member may alternatively comprise pre-formed slits, similar to the seal member of Matsumoto, or have a solid cross-section without a preformed opening prior to being pierced by separate device (col 3, ln 62 – col 4, ln 7). Thus, since a seal without a pre-formed opening is a known alternative to a seal with pre-formed slits, it would have been obvious to modify the device of Matsumoto such that the seal did not have a pre-formed opening. Matsumoto teaches the material of the seal member and the arrangement of the seal member within the valve body provides a liquid-tight or air-tight seal, and thus it would

be obvious the modified version of the device, with an initially solid cross-section, would also have the feature of being capable of maintaining a vacuum.

8. Applicant argues Kranys does not appear to teach a seal that is capable of maintaining a vacuum and thus the combination does not teach the claimed invention. The examiner respectfully notes the Kranys reference is cited to teach a valve having pre-formed slits and a valve that does not include a pre-formed opening are functional equivalents - i.e. each is capable of being penetrated by a catheter or other instrument while performing a self-sealing function. The modification does not necessarily require the material of Kranys' seal to replace the material of Matsumoto's seal. Furthermore, it is noted that Kranys teaches the open cell foam is one possible material and that when such a material is used it is preferable to incorporate a hydrophobic material to prevent blood from migrating through the open cell foam material (col 2, ll 32-53).

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached Monday through Friday, 8:30am – 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Gary Jackson, at (571) 272-4697***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

***If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to***

***TC3700\_Workgroup\_D\_Inquiries@uspto.gov.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine M Dowe/  
Primary Examiner, Art Unit 3734

February 9, 2012